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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : G01B 17/00

A2

(11) International Publication Number: WO 00/34739

(43) International Publication Date: 15 June 2000 (15.06.00)

(21) International Application Number: PCT/GB99/04102

(22) International Filing Date: 6 December 1999 (06.12.99)

(30) Priority Data:

9827160.4	10 December 1998 (10.12.98)	GB
9913993.3	17 June 1999 (17.06.99)	GB
9914923.9	28 June 1999 (28.06.99)	GB
9915481.7	5 July 1999 (05.07.99)	GB

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

Without international search report and to be republished upon receipt of that report.

(54) Title: METHOD FOR THE MANUFACTURE OF HEARING AID SHELLS

(57) Abstract

This is a method for the manufacture of hearing aid shells that is more accurate and faster than present techniques. The method involves the use of a specially adapted ultrasonic probe head to safely measure the contours of the ear canal without contact with the surface being measured. The recording of the data in the ear canal is made possible by filling the canal with a liquid and using an ear stopper, at the entrance to the ear, that incorporates a probe guiding tube to ensure that no extraneous movement occurs during the measurement process. The probe head can either be withdrawn from the ear canal by means of a motor to record the shape data or, alternatively, remained fixed relative to the ear, the scanning being accomplished by electrically recording the data from a series of fixed transducer rings located along the longitudinal axis of the probe. The three–dimensional shape data is then processed in a computer that produces a digital image STL file. The processing involves the use of an image edge detection algorithm that allows only the data that maps the surface of the ear canal to be stored, rejecting the reflected ultrasonic signal data from under the surface of the ear canal. This image file is then transmitted directly to a rapid prototyping system or recorded onto a compact disc which is used by a remote rapid prototyping system to produce an accurate tearing aid shell that is a precise fit for the ear canal. The image file can also be transmitted directly to the rapid prototyping system by means of the Internet or a direct computer to computer phone connection without the requirement to produce a compact disc. The measurement system can be used to monitor the shape of the ear canal for medical diagnostic purposes as well as the measurement of the shape of any enclosed surface of a natural or man–made structure.

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Method for the manufacture of hearing aid shells.

This invention relates to the process of manufacturing hearing aid shells.

Hearing aid shells are currently manufactured by making an impression of a patient's ear canal by means of injecting a liquid silicon rubber compound into the canal and allowing it to solidify. This mould is then withdrawn from the ear and sent to a laboratory where a master casting mould is made that is used to cast the patient's hearing aid shell. This process is far from ideal as the silicon rubber compound shrinks during the curing stage resulting in an imperfect mould being cast . This requires that the shell be sent back to the laboratory for shape modification, a number of times, before a proper fit can be obtained. The process is also critically dependent on the skill of the individual hearing aid practitioner during the injection stage,resulting in a considerable variability of the accuracy of the impressions. Elderly patients can, in some cases, experience considerable pain due to the pressure of the silicon rubber compound on sensitive areas of their ear canal when it is injected into the ear. In addition , due to these factors, the whole process is very inefficient and time consuming , resulting in the patient waiting for a considerable period of time before receiving a properly fitting hearing aid.

This invention obviates these problems by means of the following process.This entails the use of a non-contacting , ultrasonic probe, that has been developed for arterial imaging, and that images the shape of the ear canal cavity and relays this information to an image processing computer where a digital image file of the ear canal's shape is created. This file is then used in conjunction with a rapid prototyping setup such as stereo lithography,selective laser sintering , laminated object modelling , inkjet modelling , fused deposition modelling, 3DP the three dimensional printing system of the Massachusetts Institute of Technology, and any other rapid prototyping system that produces real models from computer mathematical models to manufacture the hearing aid shell that accurately fits the ear canal.

Specific embodiments of the invention will now be described by way of example with reference to the accompanying diagrams in which :-

Figure 1 shows a block diagram of the process where the electrical signal that contains the shape information from the ultrasonic probe (1) is fed into the image processing computer (2) that also incorporates the control electronics that generate the appropriate signals for the transmission and reception of the ultrasonic signals required for the operation of the probe . After processing and enhancement that includes the use of an edge detection algorithm that detects the boundary between the ear canal wall and the liquid used for acoustically coupling the ultrasonic waves from the transducer to the wall ,multiple cross-sectional views of

the ear canal can be viewed and manipulated on a monitor. Edge detection is necessary as the ultrasonic waves give reflected signals over a range of different depths of the wall's thickness. A digital image file of the shape of the ear canal is then transmitted directly to a rapid prototyping system (4) or recorded onto a compact disc (3) that is used in a rapid prototyping system (4) to produce an accurate hearing aid shell (5).

Figure 2 shows the location of the ultrasonic probe (6) in the ear canal (7). Here multiple transmitter/receiver transducers (8) positioned around the circumference of the probe sequentially record the cross-sectional shape of the canal acting like minature pulsed radar systems. This measurement is repeated for adjacent sections of the canal by means of a stepper motor controlled actuator (9) that withdraws the probe incrementally from the canal until the required area has been measured.The accuracy along the longitudinal axis of the ear canal depends on the size of each increment , 1 to 3 mm. being typical values.

Figure 3 shows an embodiment of the ultrasonic probe head (10) where a coherent fibre optic bundle (11) is incorporated into the central region of the probe to allow the practitioner to determine a safe position of the head of the probe with respect to the tympanic membrane ,(ear drum), (12), the image being viewed on a separate monitor.Illumination of the ear drum is accomplished by means of an incoherent fibre optic bundle , (15) wound around the coherent imaging fibre , (11). The ultrasonic transducer array (13) is wound around the coherent optical fibre (11) and the incoherent fibre (15)

Figure 4 shows how the ultrasonic probe (14) can be positioned correctly so that it does not come into contact with the ear canal during the measurement, by means of a guiding tube (15) located in a rubber ball (16) that is placed at the entrance to the patient's ear (17) .The diagram also illustrates how the patient must lie on his side during the measurement as his ear canal must be filled with a liquid e.g. a saline solution (18) in order to ensure a good transmission efficiency of the ultrasonic waves from the probe to the wall of the ear canal (7) and back.

Figure 5 shows a variation of the ultrasonic probe (19) that has a plastic tip (20) located at the end of the probe (21) to allow it to rest gently against a protective cover (22) that prevents the ear drum (23) from being damaged by the end of the probe (21). The measurement process with this probe is exactly the same as that used for the fibre optic/ultrasonic probe described in Figure 3 .

Figure 6 shows another embodiment of the ultrasonic probe (24) that has a single or an array of the ultrasonic transducers (25) positioned at the end of the probe in order that they can measure the distance from the ear drum (23) to the end of the probe (21) as well as the circumferential array of transducers (8) that measure the cross-sectional shape of the wall of the ear canal (7) as shown in figure 2. This measurement is displayed on a monitor's screen to allow the practitioner to position the end of the probe (21) at a safe distance in front of the

ear drum (23). An audible and or a visible warning can be incorporated into the system to alert the practitioner whenever the end of the probe (21) gets dangerously close to the ear drum (23)

Figure 7 shows another embodiment of the ultrasonic probe where the ultrasonic transducers (26) are positioned along the body of the probe in a series of rings , each ring consisting of a number of transducers that measure the cross-sectional shape of the ear canal at a particular location. Each ring provides a measure of the ear canal's shape at a pre-determined position along an axis normal to the ear drum. This probe allows the measurement of the whole area of the inner surface of the ear canal without moving the probe during the measurement process . The resolution of this probe is governed by the number of transducers positioned around the periphery of each ring and the spacing of the transducer's rings along the body of the probe (27).

Claims

1. A method for the manufacture of hearing aid shells comprising of a motor actuated ultrasonic probe used to acquire the shape data of the ear canal , an image processing computer , that also incorporates the driving electronics for the probe , with a specially developed edge detection algorithm used to filter the data , create a digital image file of the three-dimensional topography of the ear canal and control a stepper motor or a similar motor, that moves the ultrasonic probe in a series of linear displacements , allowing an area mapping of the topography of the ear canal to be obtained incrementally, in steps, each step providing a tomographic-type slice of the canal's cross-sectional profile , a compact disc recording system , and a rapid prototyping system used to produce accurate hearing aid shells.

2. A combined ultrasonic/fibre optic probe used to both acquire the shape data of the ear canal and to monitor the position of the probe within the canal without obstructing the field of view of either sensor. The fibre optic section consists of an inner coherent bundle of fibres and objective lens that relay the image of the canal to a C.C.D camera via the fibres , and an outer incoherent bundle of fibres that surround the coherent bundle and permits the illumination of the canal by an external light source that is optically coupled to the other end of the incoherent bundle. The array of ultrasonic transducers is wound around the fibre optic bundles , present technology allowing up to 64 equally spaced transducer elements and their related circuitery to be located on and within the probe. Each transducer emits an ultrasonic sound impulse, normal to the body of the probe, which is then reflected by the wall of the ear canal back to the transducer which now acts as a receiver. A measurement of the time elapsed between the transmission and the reception of the pulse allows the distance to be calculated as the velocity of sound in the liquid medium filling the ear is a constant known value.This measurement is repeated for up to 64 transducers located around the periphery of the probe .As well as measuring the ear canal's shape , this probe allows the direct visual verification, for the practitioner, of the safe position of the end of the probe relative to the ear drum thereby preventing any damage to the ear drum by the end of the probe.

3. An alternative ultrasonic probe head to that described in 2. where the fibre optic elements are replaced by either a single or an array of the ultrasonic transducers mounted on the end of the probe to allow the measurement of the distance of the end of the probe to the ear drum. This probe head also incorporates the circumferential array of transducers , already described in claim 2, that measure the shape of the wall of the ear canal.

4. A rubber or other flexible material stopper located at the entrance to the ear incorporating a cylindrical stainless steel tube that runs the complete length of the stopper, through the centre, in order to act as a guide for the ultrasonic probe.

The stopper is spherical in shape or other shape consistent with establishing a non moving fit at the entrance to the ear drum in order to provide a fixed support for the probe relative to the ear. The diameter of the tube is made a little larger than the probe in order to allow the probe's smooth passage into the ear canal.This is designed to keep the probe in a fixed position relative to the side wall of the ear canal during the withdrawal of the probe by a small motor located on top of the stopper. This minimises the errors due to any relative displacements between the probe and the wall of the ear canal as the meaurement is being recorded . The small motor, which can be a stepper motor or other motor capable of being controlled by the computer, allows the probe to be withdrawn from the ear with a range of selectable, steady speeds to facilitate the three-dimensional measurement of the ear canal's surface topography by the creation of a digital image file of a series of cross-sectional measurements, of the ear canal, recorded in steps by the probe .The motor is mounted on top of the stopper to prevent any relative movement between it and the probe as the probe is withdrawn from the ear. The accuracy of the measurement of the ear canal's topography along the surface normal to the cross sectional planes is dependent on the length of the incremental step between the planes during the recording phase of the measurement . The computer can be programmed to alter the step size induced by the motor to give the accuracy required by the practitioner.

5. The use of an ultrasonic probe catheter to carry out the measurement as described in claim 1. Here a protective cover is placed over the tympanic membrane , (the ear drum) , and the probe is inserted into the ear canal until it rests on the protective cover. The end of the probe is constructed so as to have a soft tip in plastic, rubber or similar biologically safe material that will not penetrate the protective cover. The technique described in claim 3 to position and control the movement of the probe is used in exactly the same way as that described for the combined ultrasonic/fibre optic probe .The visual indication of the safe position of the probe described in claim 2 is replaced by the physical prevention of this probe, in reaching the ear drum, by the protective cover.

6. The use of a saline solution or other biologically safe fluid to be poured or injected into the ear canal in order to allow the good conduction of ultrasonic sound waves from the transducers to the wall of the ear canal during the measurement procedure. The patient should lie on his side with his head supported in order that the solution does not spill out of the ear during the measurement.

7. The data in the image file of the ear canal's shape can be transmitted to a rapid prototyping system adjacent to the computer or transmitted by the Internet or a computer to computer telephone connection to a central rapid prototyping system.

8. An alternative embodiment of the ultrasonic probe where the transducers are positioned along the body of the probe as a series of rings of ultrasonic

transducers where each ring consists of a number of equally spaced transducers around the periphery of the probe. The claims described in 2,3,4,5,6,7 also apply to this probe with the exception that no motor is required to move the probe relative to the ear canal when a measurement is being made .

9. The use of an edge detection algorithm is important when the data from the ultrasonic transducers is processed in the computer as the rapid prototyping system requires only information about the surface shape of the ear canal. The use of the algorithm allows the ultrasonic reflections from areas underneath the surface of the ear canal to be rejected.

10. This technique described in claims 1 to 9 can also provide useful medical information about the shape of the ear canal for diagnostic purposes including the monitoring of the change of shape that can occur, for example, due to cancerous growths and other conditions where a knowledge of the shape or change of shape is important .

11. This technique , described in claims 1 to 9 , can also be used for non medical applications such as the measurement and the replication of the shape of enclosed volumes , pipes , cavities , and voids in any structure both natural and artificial.

Figure.1

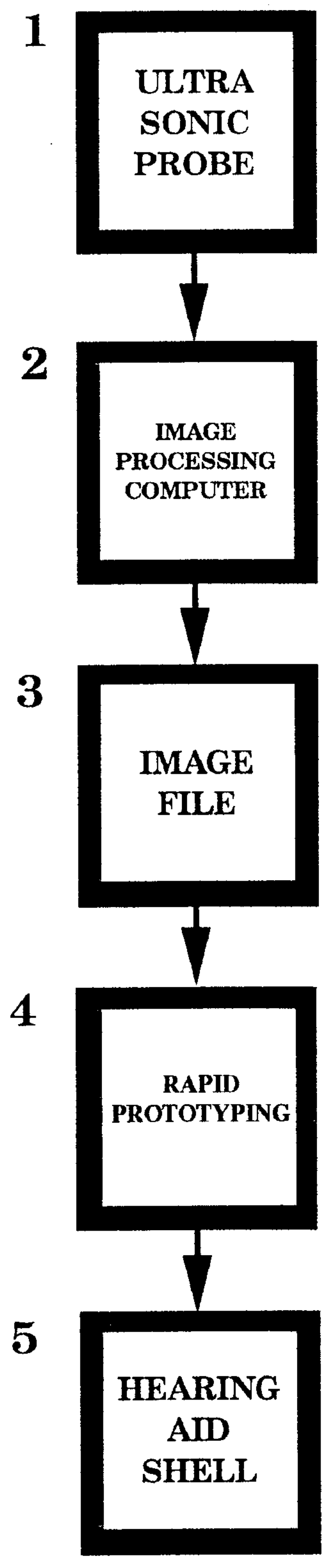
1
ULTRA SONIC PROBE
2
IMAGE PROCESSING COMPUTER
3
IMAGE FILE
4
RAPID PROTOTYPING
5
HEARING AID SHELL

Figure.2

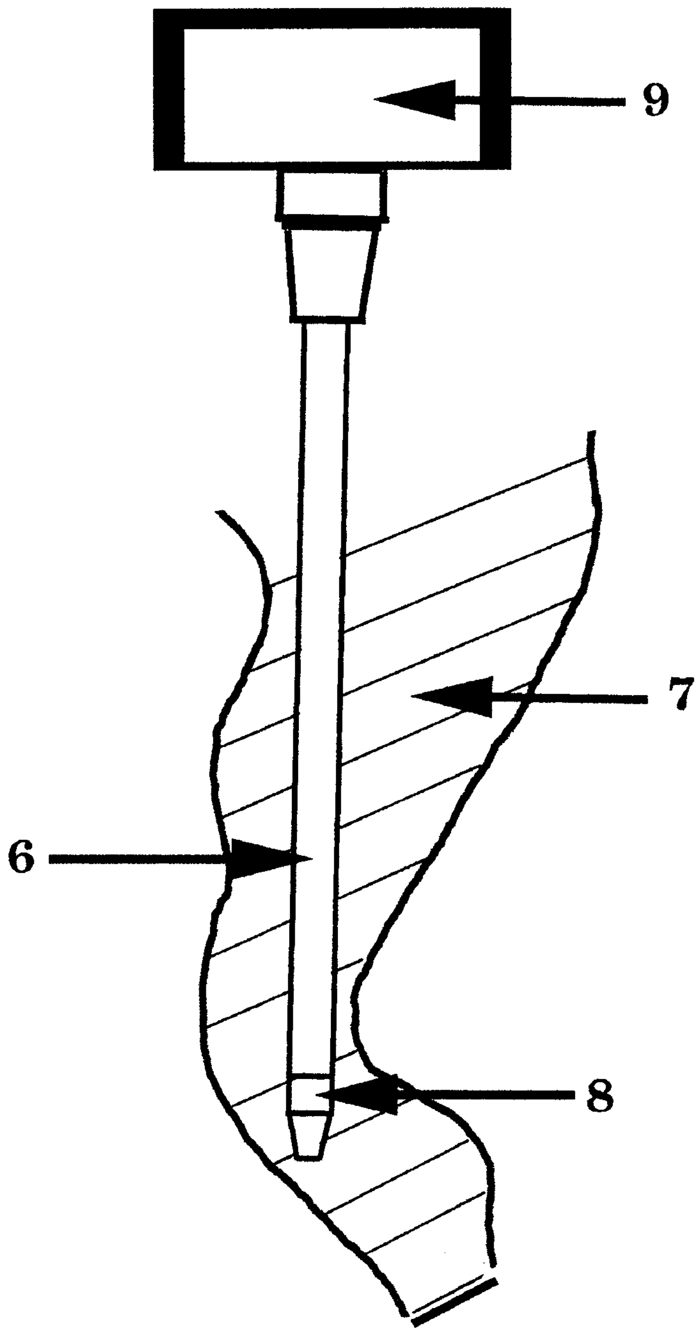

Figure.3

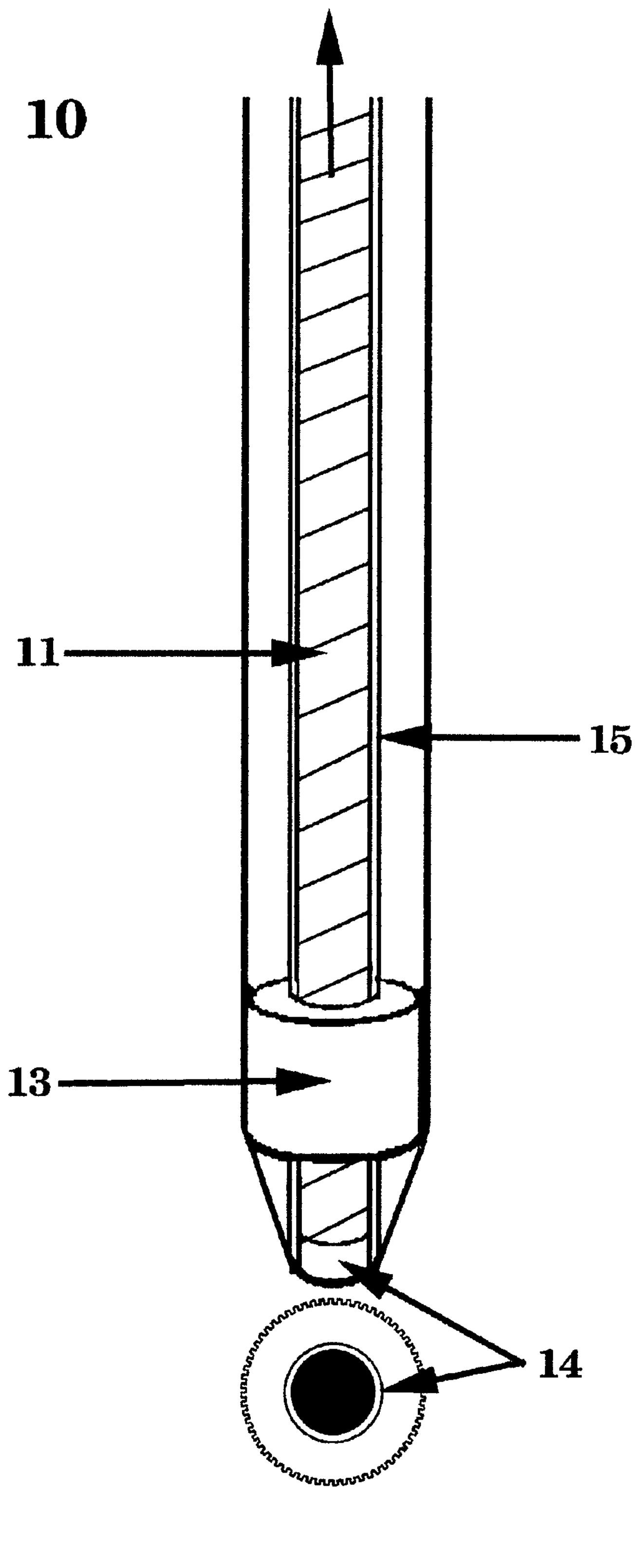

Figure.4

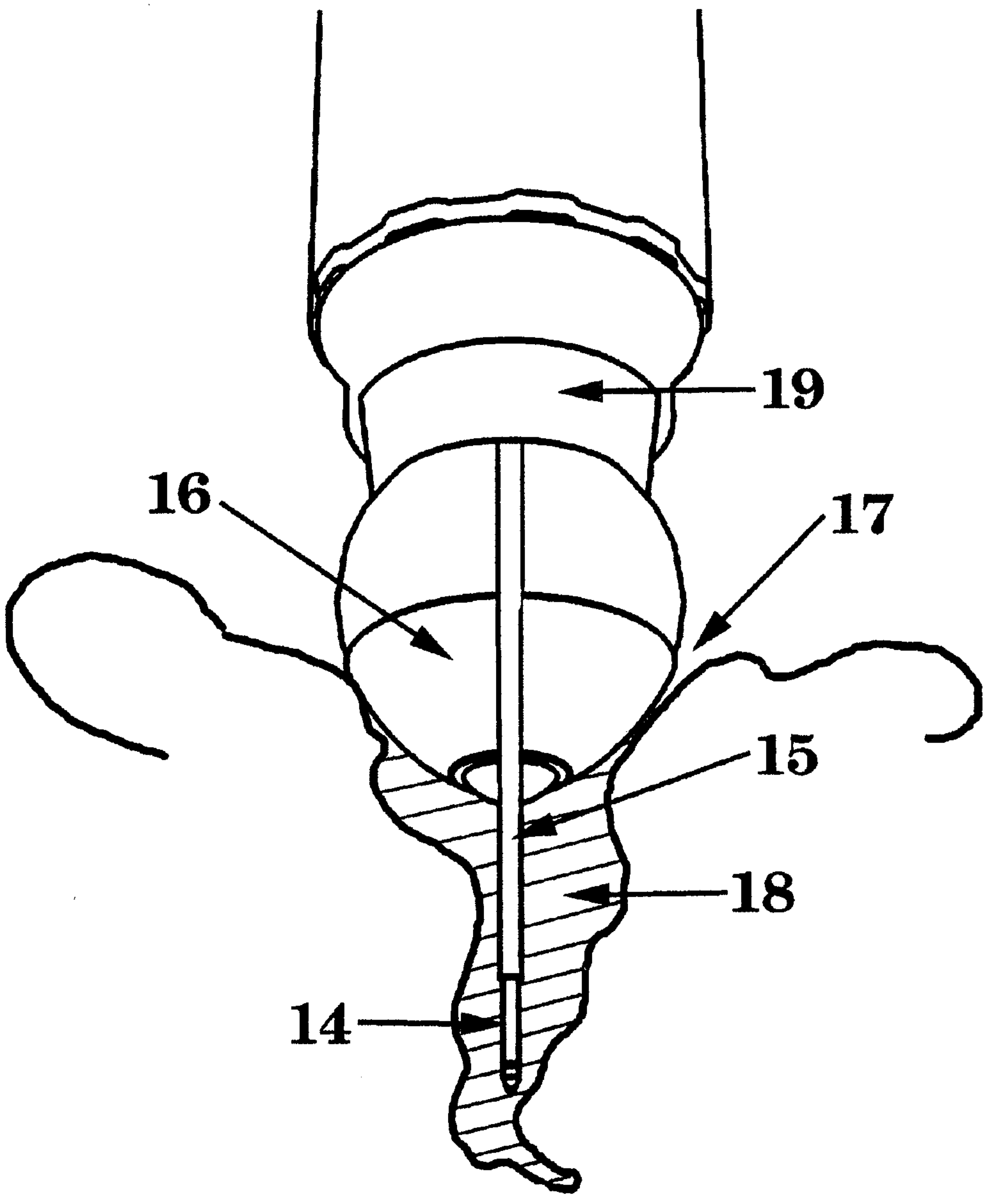

Figure.5

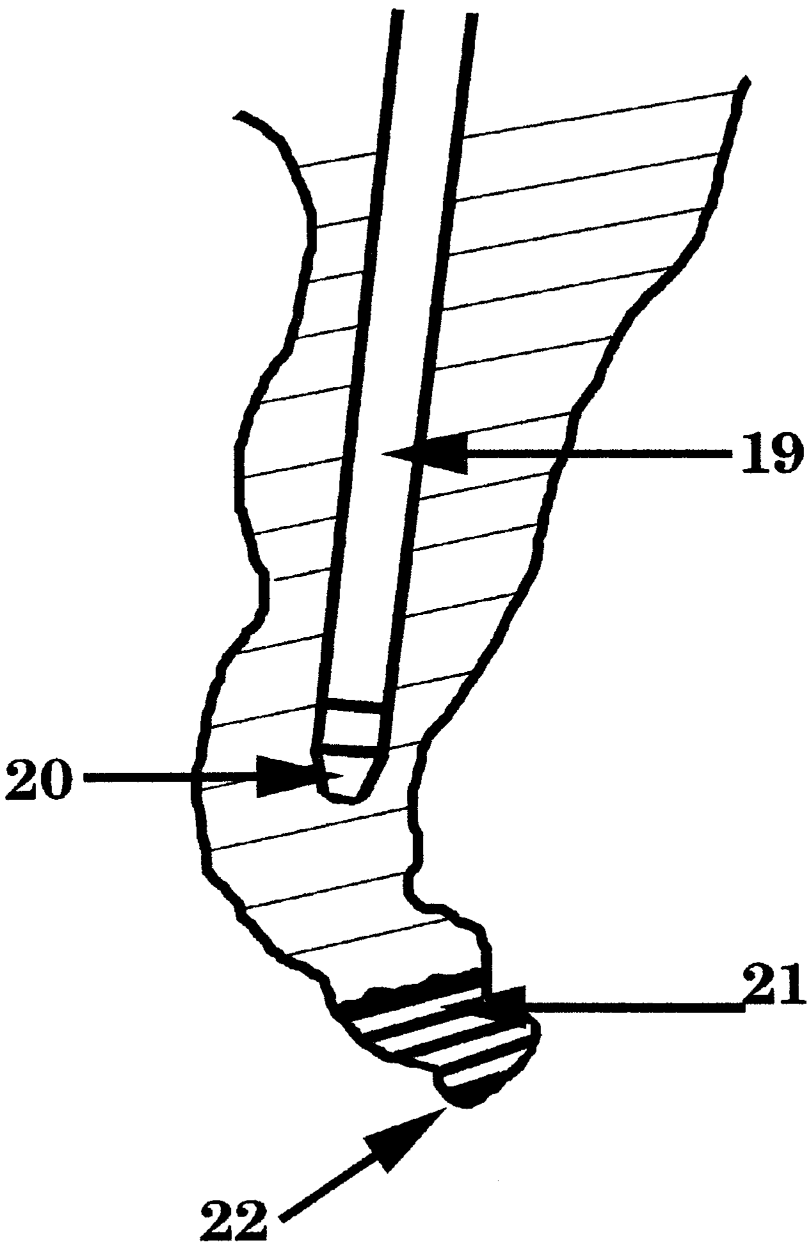

Figure.6

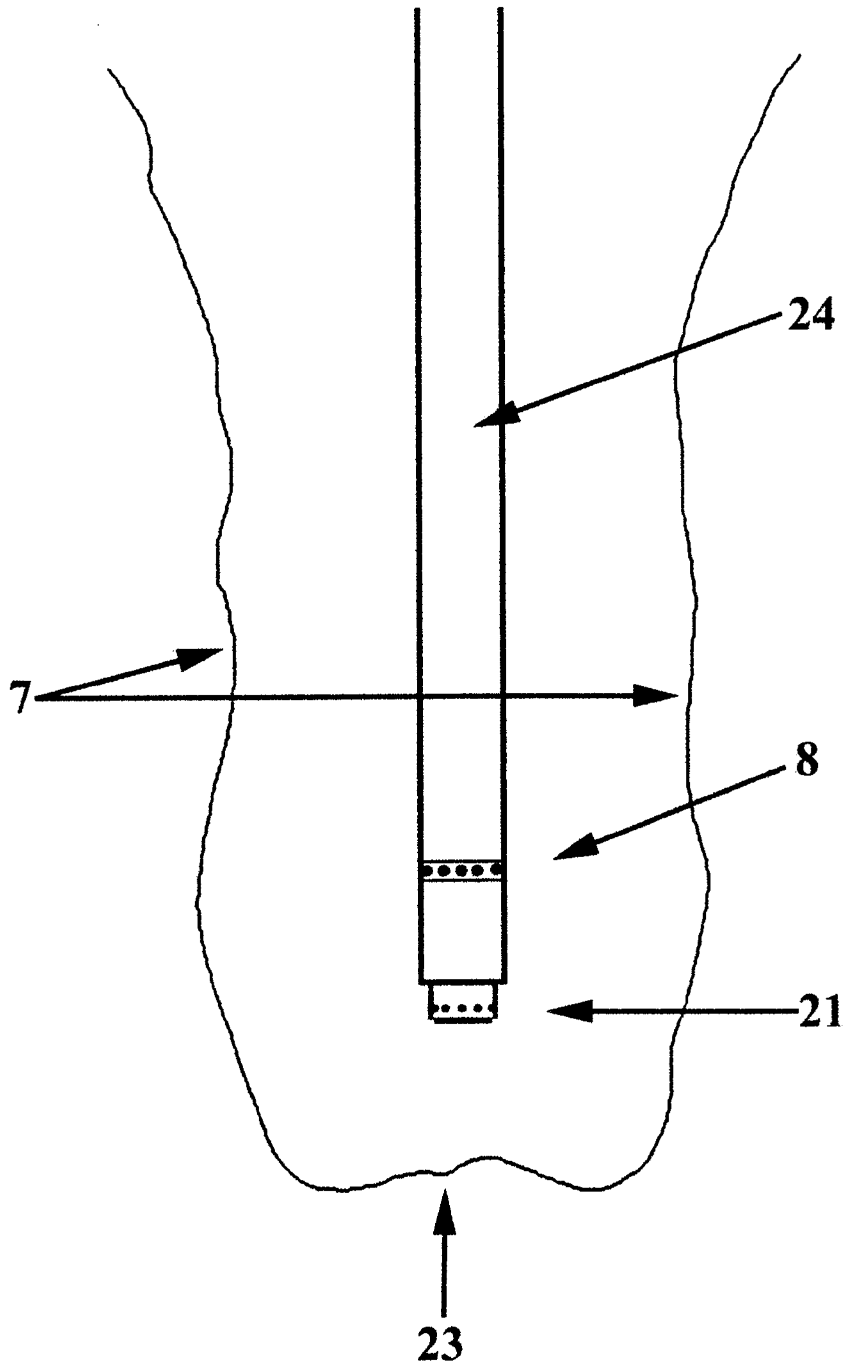

Figure.7